UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ETHICON ENDO-SURGERY, INC. and ETHICON ENDO-SURGERY, LLC, *Plaintiffs and Counterclaim-Defendants*, v. COVIDIEN LP, COVIDIEN SALES LLC, and COVIDIEN AG, *Defendants and Counterclaim-Plaintiffs*.	)	Civil Action No. 1:16-cv-12556-LTS **LEAVE TO FILE UNREDACTED VERSION UNDER SEAL GRANTED ON APRIL 25, 2017 (DKT. NO. 36)** **LEAVE TO FILE EXCESS PAGES GRANTED ON MAY 2, 2017 (DKT. NO. 43)**

MEMORANDUM IN SUPPORT OF DEFENDANTS AND COUNTERCLAIM-PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Covidien's pioneering LigaSure™ product line has set the industry standard for advanced bipolar vessel sealing devices for almost 20 years, leading to increased safety and better outcomes for millions of patients. Consistent and reliable vessel seals are synonymous with the LigaSure product line: when a surgeon uses a LigaSure device in surgery, that surgeon knows it will deliver a consistent and reliable seal every time. The Covidien patents in this case are directed to performance and safety features that provide the backbone for the entire LigaSure platform, including the features that enable the LigaSure devices to provide consistent and reliable vessel seals. Today, Covidien (now owned by Medtronic) is the clear market leader in the advanced bipolar segment of the advanced energy market [redacted] due in large part to the fact that LigaSure is an advanced bipolar product that is recognized for delivering consistent and reliable vessel seals time and time again.

For years, Covidien's fiercest competitor—Ethicon—has lived in Covidien's shadow in the advanced bipolar segment. Ethicon has made several, substantial attempts to emerge from this shadow, most notably through its acquisition of the Enseal product line in 2008, followed by its launch of the Enseal® G2 line of devices in 2011. These attempts were unsuccessful and rejected in the marketplace, due in large part to Enseal's historical failure to deliver consistent and reliable vessel seals. Incapable of delivering sealing technology that could perform on par with Covidien's LigaSure, and desperate to gain some traction in the market, Ethicon recently launched the Enseal X1 Large Jaw ("Enseal X1"). In this latest attempt to deliver a sealing performance that is comparable to Covidien's LigaSure devices, Ethicon infringes Covidien's valuable and market-making patented technology. Adding insult to injury, Ethicon explicitly touts the Enseal X1 as a replacement for Covidien's LigaSure products, and denigrates LigaSure's sealing performance in its marketing and promotional materials.

Before it even launched the product, Ethicon recognized the Enseal X1 infringed Covidien's U.S. Patent No. 8,241,284 ("the '284 patent"). But, instead of making a meaningful effort to design its product to avoid the '284 patent, Ethicon attempted—unsuccessfully—to eliminate the patent by filing two, back-to-back petitions for *inter partes* review ("IPR") challenging the validity of the '284 patent. The United States Patent and Trademark Office ("USPTO") rejected both of those challenges, criticized Ethicon's tactics, and twice reaffirmed the validity of Covidien's '284 patent.

Covidien's share in the advanced bipolar market is hard-fought and earned. It is due to Covidien's substantial research and development efforts, proprietary innovations, and LigaSure's singular ability to deliver consistent and reliable vessel seals to surgeons time and time again. Faced with competing against its own patented technology in the marketplace at significantly reduced prices, and with threat of the foreclosure from existing customer accounts to Ethicon due to the Enseal X1, Covidien has no other recourse but to seek a preliminary injunction preventing Ethicon's infringement. While a preliminary injunction is, at times, considered an extraordinary measure, the circumstances here warrant this remedy. Each of the preliminary injunction factors considered by courts strongly weigh in favor of an injunction here.

First, Covidien is likely to succeed on the merits. The Enseal X1 includes every limitation of claim 1 of the '284 patent. Indeed, that is precisely why Ethicon twice attempted to challenge the validity of the '284 patent *before* the Enseal X1 was even launched, and in both instances, the PTAB declined to institute Ethicon's validity challenges.

Second, Covidien is being irreparably harmed in the market by Ethicon's use of Covidien's own technology to take LigaSure market share. Indeed, Covidien is *already* losing substantial sales and longstanding customer relationships to the Enseal X1 just over one month

after Ethicon's commercial launch of the product. There is no measure of monetary damages that could sufficiently address the harm to Covidien from Ethicon's infringement, which includes lost profits, lost market share, and lost customer relationships both now and in the future, as well as reputational harm resulting from Ethicon's aggressive marketing campaign. Ethicon's marketing for the Enseal X1 aims directly at Covidien's LigaSure Impact device, particularly its vessel sealing performance. In addition, Ethicon is selling Enseal X1 at a substantially lower price than the LigaSure Impact device, in order to convince customers to purchase the Enseal X1 instead of LigaSure Impact and move those customers to make a large-scale shift from being a dual-source customer (a customer of both Ethicon and Covidien advanced energy devices) to a sole-source customer (Ethicon only). Stated simply, Ethicon has taken Covidien's intellectual property and is now using that stolen property to destroy Covidien's reputation and standing in the marketplace. This harm cannot be compensated solely by monetary damages.

Third, the balance of equities strongly weighs in Covidien's favor, as Ethicon elected to market and sell an infringing product despite being well-aware of, and twice attempting and failing to defeat, the '284 patent. While Covidien acknowledges the competitive nature of the marketplace, Ethicon should not be permitted to enhance its product offerings and take Covidien's market share by infringing Covidien's intellectual property rights.

Fourth, the public interest will not be harmed because the Enseal X1 was only recently launched, and there are other available alternatives on the market, including Covidien's LigaSure products. To the contrary, the public interest supports enforcing Covidien's patent rights, particularly in view of the USPTO's decisions reaffirming the validity of the'284 patent.

A preliminary injunction is necessary to prevent any further infringement by Ethicon and irreparable harm to Covidien, before the Enseal X1 product is able to further penetrate the

advanced bipolar segment of the market and further cause Covidien irreversible injury. For these reasons, Covidien respectfully submits its Motion for a Preliminary Injunction.

II. FACTUAL BACKGROUND

A. Background Regarding Advanced Bipolar Surgical Instruments

The products at issue in this case are advanced energy vessel sealing instruments. Advanced energy instruments are used in many different surgical procedures, including colorectal, gynecological, bariatric, and thoracic procedures, that require dissecting blood vessels or tissue. Declaration of John Chindlund ("Chindlund Decl."), ¶ 28; s*ee also* Declaration of Richard Mulloy ("Mulloy Decl."), Mulloy Ex. 1 ('284 patent), at Col. 1:42-46. Traditionally, surgeons had difficulty suturing vessels or performing other methods of controlling patient bleeding, such as clamping or tying-off transected blood vessels, during certain surgical procedures. *Id*. Advanced energy vessel sealing instruments help solve that problem.

The broader advanced energy market consists of two distinct but partially overlapping segments. Chindlund Decl., ¶ 7. One category of devices utilizes advanced bipolar energy. *Id.* The other category utilizes ultrasonic energy. *Id.* The products at issue in this case are advanced bipolar devices, such as Covidien's pioneering LigaSure line of products, which are particularly well-suited for sealing and dissecting larger (up to 7mm in size) vessels. *Id.*, ¶ 31.

The advanced bipolar surgical instruments at issue in this case have an active portion at one end, which includes opposing jaw members located at the end of an elongated shaft, and a hand-held portion at the other end, which the surgeon squeezes to actuate the jaw members between an open and closed position to grasp tissue. Chindlund Decl., ¶ 8. The device connects to an energy source, such as an electrosurgical generator. *Id.* Through a series of electrical connections, the energy source provides bipolar RF energy to the pair of jaw members. *Id.* When tissue is clamped between the opposing jaw members and the device is activated, each jaw

member conducts bipolar RF energy through the tissue. *Id.*, ¶ 12. The combination of mechanical clamping pressure, gap distance between the jaw members, and electrical energy provides a tissue seal that stops or slows patient bleeding. *See* Mulloy Ex. 1, at Col. 1:30-34, 1:53-2:5; *see also* Declaration of William Durfee ("Durfee Decl."), ¶ 11. These instruments thus allow surgeons to make precise cuts during surgery with limited patient blood loss, which improves patient outcomes. Chindlund Decl., ¶ 6.

B. Covidien's Market-Leading LigaSure Products

Covidien, acquired by Medtronic in 2015, is one of the world's largest manufacturers of advanced energy surgical instruments. Since its introduction in 1998, Covidien's pioneering LigaSure line of products has set the industry standard for advanced energy vessel sealing instruments. *See* Chindlund Decl., ¶ 10. LigaSure products have been used in millions of surgical procedures because they are recognized for their consistent and reliable vessel sealing. Chindlund Decl., Exs. 1 and 2 (LigaSure product literature). There are more than a dozen LigaSure products, including the LigaSure Impact, shown below:

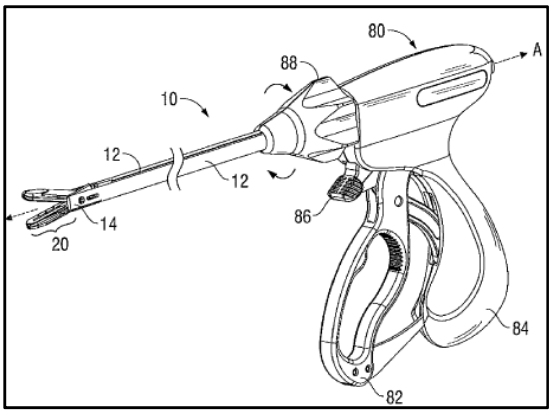
See Chindlund Decl., Ex. 2.

Through decades of innovation, Covidien created the advanced bipolar segment of the advanced energy market and differentiated its products from follow-on competitors. Covidien is the clear market leader in this segment. Chindlund Decl., ¶¶ 15, 32. The ability to provide a consistent and reliable vessel seal is a significant demand driver for the LigaSure products and

has helped to build the product line's success. *Id.*, ¶ 11. [redacted] Covidien's customers for LigaSure products include hospitals, Integrated Health Networks, and Group Purchasing Organizations ("GPOs"). Chindlund Decl., ¶ 38.

C. Covidien's '284 Patent

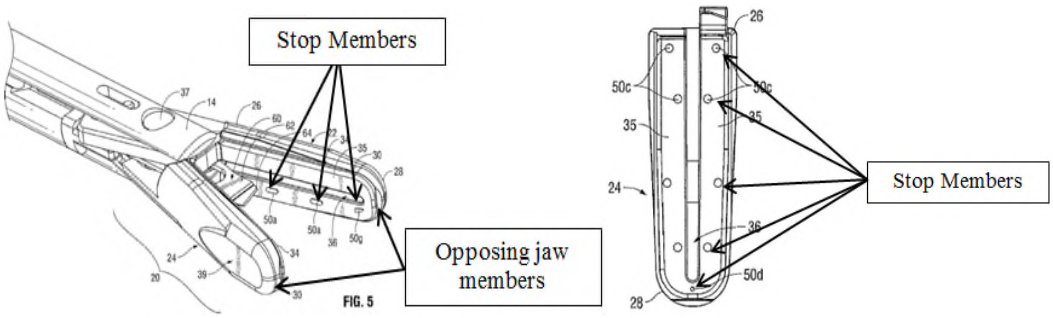
The '284 patent issued on August 14, 2012 and is titled "Vessel Sealer and Divider with Non-Conductive Stop Members." Mulloy Decl., Ex. 1, at Cover. The '284 patent describes and claims a surgical instrument that provides more consistent vessel sealing. The instrument has a handle at one end, electrically-charged jaw members at the other end, and an elongated shaft between them. Figure 1 of the '284 patent below shows these (and other) components of the device:



Mulloy Decl., Ex. 1 at Fig. 1.

The '284 patent is directed to important features that enable consistent and reliable sealing of blood vessels and tissue. "In order to effectively seal larger vessels (or tissue) two predominant mechanical parameters must be accurately controlled—the pressure applied to the vessel (tissue) and the gap distance between the electrodes" on the opposing jaw members. *See*,

e.g., Mulloy Decl., Ex. 1 at Col. 2:6-10. To regulate the gap distance, the '284 patent describes "stop members" that are "designed to control the gap distance between opposing jaw members and enhance the manipulation and gripping of tissue during the sealing and dividing process." *See* Mulloy Decl., Ex. 1, at Col. 1:23-26; *see also id.* at Col. 3:50-53. Figures 5 and 6c of the '284 patent (below) show the stop members on the inner surface of at least one of the jaw members.



By incorporating stop members that project from the inner surface of at least one of the jaw members, the '284 patent helps to ensure consistent and reliable vessel sealing by maintaining proper spacing between the two jaw members. *See* Mulloy Decl., Ex. 1, at Col. 10:60-66. Although Covidien is confident in the merits of its infringement claims regarding each of the patents asserted in this case, this motion is limited to the '284 patent due to the extensive history between the parties regarding this patent, including Ethicon's two unsuccessful IPR petitions directed to that patent as discussed below.

D. Ethicon's Infringing Product—The Enseal X1

In contrast to Covidien's longstanding success and innovation in the advanced bipolar market segment, Ethicon has struggled in this segment for years. Ethicon's only offering in that space has been the Enseal line of products, which Ethicon acquired in connection with its acquisition of SurgRx, Inc. in October 2008. *See* Chindlund Decl., ¶ 21; Mulloy Decl., Ex. 2. For nearly a decade, however, Ethicon has failed to achieve significant market success with the

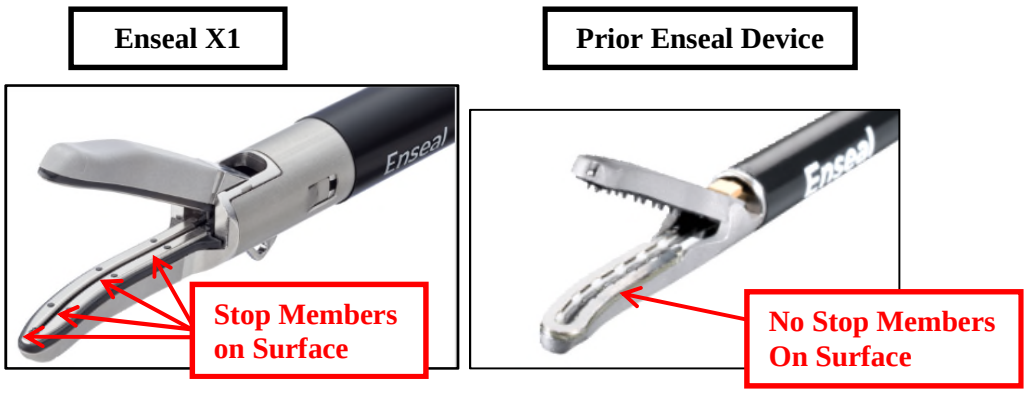
prior Enseal products. *See* Chindlund Decl., ¶¶ 21-22. Ethicon has not been able to gain substantial market share due to the Enseal line's poor performance as a vessel sealer. *Id.*, ¶ 22.

[redacted]

Due to its historic lack of success, Ethicon recently re-designed the Enseal product in an effort to better compete with Covidien's LigaSure products. The result is the Enseal X1, shown below, which Ethicon touts as the "the first" in its "new generation" of advanced bipolar offerings:

Chindlund Decl., Ex. 5 (Enseal marketing materials).

Among other things, Ethicon has re-designed the Enseal device to incorporate stop members along the jaw surface, as claimed in Covidien's '284 patent. The pictures below show the Enseal X1's jaws (on the left) with several stop members along the lower jaw's seal surface, and offers a stark contrast with a prior Enseal product (on the right) that does not include stop members on the lower jaw's seal surface:



Mulloy Decl., Exs. 4 and Ex. 10.

In September 2016, Ethicon received pre-market approval from the Food and Drug Administration ("FDA") to market the Enseal X1. Chindlund Decl., Ex. 3 (Sept. 12, 2016 press release); *see also* Mulloy Decl., Ex. 5 (510(k) approval notice). In its pre-market notification to the FDA, Ethicon stated that the Enseal X1 device is used for several different types of surgical procedures, including the same procedures for which the LigaSure Impact product is used. Mulloy Decl., Ex. 4; Chindlund Decl., Ex. 2 (LigaSure Impact™ Curved Large Jaw Open Sealer/Divider Nano-Coated Product Information Kit, 2016). In clearing the device, the FDA noted that the Enseal X1 "is substantially equivalent" to Covidien's predicate LigaSure Impact device. *See* Mulloy Decl., Ex. 4.

On March 6, 2017, Ethicon announced the commercial launch of the Enseal X1 device. Chindlund Decl., Ex. 4. While Ethicon only recently launched the product, Ethicon immediately began targeting Covidien's LigaSure Impact device in the Enseal X1's product and marketing literature in an effort to convince LigaSure customers to switch to Enseal. *See* Chindlund Decl., Ex. 5. According to Ethicon's own marketing materials, for every procedure where a Covidien LigaSure was being used, an Enseal X1 should be used instead. *Id.* Ethicon's direct targeting of LigaSure includes making several performance-based claims, including that Enseal X1 offers "better sealing compared to LigaSure Impact™ …." *Id.* Ethicon further claims that Enseal X1 offers "less bleeding," "better tissue management," and an "overall better design compared to LigaSure Impact." *Id.* Indeed, LigaSure is the *only* competitive device mentioned in Ethicon's marketing materials, and Ethicon explicitly markets the Enseal X1 device as an "alternative" to "replace" Covidien's LigaSure Impact product. Chindlund Decl., Ex. 6 (Ethicon Enseal X1 product literature).

E. Litigation and Procedural History

There is no dispute that Ethicon and Covidien have an extensive litigation history. *See* Dkt. No. 1 at ¶¶ 30-40. To minimize or avoid future litigation, the parties previously agreed on an alternative dispute resolution procedure set forth in a 1999 settlement agreement. *Id.*

Before reaching out to Covidien pursuant to the 1999 settlement agreement to address patent issues related to the Enseal X1, Ethicon recognized that the new Enseal X1 design had infringement problems with Covidien's '284 patent. As a result, Ethicon attempted to challenge the validity of the '284 patent instead of designing the Enseal X1 to avoid the claims. In May 2015, Ethicon filed its first petition for IPR challenging the validity of the '284 patent. Mulloy Decl., Ex. 5 (*Ethicon Endo-Surgery, Inc. v. Covidien AG*, IPR2015-01275, Paper No. 1 (May 27, 2015)). On December 17, 2015, a panel of the USPTO's Patent Trial and Appeal Board ("PTAB") denied Ethicon's petition, noting that Ethicon "has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim." Mulloy Decl., Ex. 6 (*Ethicon Endo-Surgery, Inc. v. Covidien AG*, IPR2016-00944, Paper No. 8, at 2 (Oct. 24, 2016)).

Ethicon later wrote to Covidien in May 2016 expressing its plan to commercialize a new generation Enseal device and attempting to invoke the dispute resolution procedures in the agreement. Dkt. No. 1 at ¶ 42. On April 29, 2016—after it already submitted a request for approval of the Enseal X1 to the FDA (*see* Mulloy Decl., Ex. 7)—Ethicon filed yet another petition for IPR challenging the validity of the '284 patent. Mulloy Decl., Ex.8 (*Ethicon Endo-Surgery, Inc. v. Covidien AG*, IPR2016-00944, Paper No. 1, at 2 (Apr. 29, 2016)). The PTAB again rejected Ethicon's arguments, and criticized Ethicon's serial attacks on the '284 patent: "The America Invents Act was enacted to provide a speedy and inexpensive alternative to challenging patent validity in district courts. It does not, however, sanction repeated

administrative attacks on the patentability of a claim." Mulloy Decl., Ex. 9 (*Ethicon Endo-Surgery, Inc. v. Covidien AG*, IPR2016-00944, Paper No. 8, at 2 (Oct. 24, 2016)). During this time, although Covidien disagreed that dispute resolution was appropriate before the Enseal X1 product was commercially launched, the parties did ultimately engage in attempted dispute resolution related to the '284 patent, among other patents.

After having twice failed in its efforts to challenge the validity of the claims of the '284 patent, Ethicon changed course and initiated this lawsuit on December 19, 2016, seeking a declaratory judgment that the Enseal X1 does not infringe five Covidien patents, including the '284 patent. Dkt. No. 1. On February 14, 2017, Covidien counterclaimed for infringement of the patents identified by Ethicon. Dkt. No. 14. Covidien filed an amended answer and counterclaims on March 28, 2017, and filed a second amended answer and counterclaims on April 24, 2017, asserting additional patents not previously identified by Ethicon and eliminating other patents from the litigation. Dkt. Nos. 21, 34.

III. LEGAL STANDARDS FOR PRELIMINARY INJUNCTION

Courts evaluate four factors in determining whether to grant a preliminary injunction: (1) a likelihood of success on the merits; (2) a likelihood of irreparable harm; (3) the balance of equities; and (4) whether the injunction is in the public interest. *See Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7 (2008). Several courts have granted preliminary injunctions in patent cases when faced with the type of irreparable harm from a direct competitor at issue in this case. *See, e.g., Celsis In Vitro, Inc. v. CellzDirect, Inc*., 664 F.3d 922, 930 (Fed. Cir. 2012); *Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1170 (Fed. Cir. 2014).

IV. COVIDIEN'S MOTION FOR A PRELIMINARY INJUNCTION SHOULD BE GRANTED

A. Covidien is Likely to Succeed on the Merits of its Patent Infringement Claim

Patent infringement is the unauthorized making, using, offering to sell, or selling of a claimed invention. 35 U.S.C.A. § 271. "Infringement of a claim requires that the accused device meet every limitation of the claim, either literally or by equivalents." *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1178 (Fed. Cir. 1991). "For a patentee to establish that it is likely to succeed on the merits, it must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049-50 (Fed. Cir. 2010) (citations omitted). Covidien is likely to succeed on the merits because the Enseal X1 includes every limitation of claim 1 of the '284 patent, and claim 1 of the '284 patent has already withstood validity challenges by Ethicon.

1. Ethicon Infringes Claim 1 of the '284 Patent

As discussed above, the '284 patent is directed, in part, to an advanced energy surgical instrument with "stop member" features on the surface of at least one of the jaws that are configured to maintain a uniform gap distance between the opposing jaws. *See* Mulloy Decl., Ex. 1, at Col. 1:19-26, Col. 2:6-10. Claim 1 of the '284 patent states:

> 1. An endoscopic bipolar forceps, comprising:
>
> an elongated shaft having opposing jaw members at a distal end thereof, the jaw members including a length and a periphery and movable relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween, the jaw members each including respective flat seal surfaces extending along a respective length thereof and adaptable to connect to a source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal;

> a plurality of non-conductive stop members disposed along the length of at least one of the seal surfaces of at least one of the jaw members such that the plurality of non-conductive stop members are disposed along the same plane on the seal surface with respect to one another, the non-conductive stop members configured to maintain a uniform distance between the jaw members along the length thereof; and
>
> a knife disposed in operative communication with at least one of the jaw members and translatable to sever tissue disposed between jaw member.

Id. at Col. 13:50-14:6.

a. Claim Preamble: An endoscopic bipolar forceps, comprising…

It is a well-established principle of patent claim construction that the preamble of a claim is not treated as limiting the scope of the claim, absent special circumstances. *Aspex Eyewear, Inc. v. Marchon Eyewear, Inc.*, 672 F.3d 1335, 1347 (Fed. Cir. 2012) ("[A]s a general rule preamble language is not treated as limiting."). "Absent clear reliance on the preamble in the prosecution history, or in situations where it is necessary to provide antecedent basis for the body of the claim, the preamble generally is not limiting." *Symantec Corp. v. Computer Assocs. Int'l*, 522 F.3d 1279, 1288 (Fed. Cir. 2008) (citations omitted).

Here, the preamble of "[a]n endoscopic bipolar forceps, comprising" is not limiting because none of the exceptions to the general rule are present in this case. The patentee did not rely on the preamble during prosecution (or otherwise suggest that the preamble was limiting), and the remaining elements of claim 1 do not depend on the preamble for any antecedent basis. The claim would read identically if the preamble were merely replaced with "apparatus."

If the claim preamble is construed to be limiting, however, the Enseal X1 product practices the preamble. Durfee Decl., ¶¶ 24-27. The Enseal X1 includes the same features as the

bipolar forceps recited in claim 1 of the '284 patent, and is designed such that it fits through an endoscopic trocar and cannula. *Id.*, ¶¶ 25-27; *see also* Mulloy Decl., Ex. 1, at Col. 1:35-41.[1]

b. …an elongated shaft having opposing jaw members at a distal end thereof…

The Enseal X1 includes an elongated shaft with opposing jaw members at the distal end of the shaft. Durfee Decl., ¶¶ 28-29. The shaft and jaw members of the Enseal X1 are shown below:

c. …the jaw members including a length and a periphery and movable relative to one another from a first position wherein the jaw members are disposed in spaced relation relative to one another to a second position wherein the jaw members cooperate to grasp tissue therebetween…

The Enseal X1 has jaw members—one movable and one stationary—with a length and a periphery, that are movable relative to one another. Durfee Decl., ¶¶ 30-31. The jaws move from a first to a second position when a user operates the device handle. *Id.*, ¶¶ 31-33. In the second position, the jaw members of the Enseal X1 cooperate to grasp tissue between them. *Id.*, ¶ 34. Indeed, Ethicon's 510(k) approval for the Enseal X1 describes the instrument as "a bipolar electrosurgical instrument" used "to cut and seal vessels, cut, ***grasp***, and dissect tissue during surgery." Mulloy Decl., Ex. 7 (510(k) summary)) (emphasis added). The images below show the jaws of the Enseal X1 in first and second positions.

[1] Ethicon's Complaint—which identifies several features of the Covidien patents it claims are not present in the Enseal X1 products—does not dispute that the Enseal X1 practices the preamble of claim 1 of the '284 patent. *See* Dkt. No. 1 at ¶¶ 87-89.

first position

second position

d. ...the jaw members each including respective flat seal surfaces extending along a respective length thereof…

Each opposing jaw member in the Enseal X1 has an inner-facing, flat surface (*i.e.*, seal surface) along the length of the jaw. Durfee Decl., ¶¶ 35-36. The flat seal surfaces of the opposing jaw members come together as the movable jaw pivots toward the fixed jaw. *Id.*, ¶¶ 36-37.

flat seal surface on lower jaw

flat seal surface on upper jaw

e. …[the jaw members]…adaptable to connect to a source of electrical energy such that the jaw members are capable of conducting energy through tissue held therebetween to effect a tissue seal…

The Enseal X1 utilizes a source of electrosurgical energy, *i.e.*, a generator, adapted to connect (through internal electrical pathways in the device) to each jaw member such that each jaw member is capable of conducting energy to tissue held between the jaw members, in order to effect a tissue seal. Durfee Decl., ¶¶ 38-41. The Enseal X1 marketing literature and 510(k) premarket notification both indicate that the product is used with the Ethicon Generator GEN11

(or G11), which "provides radiofrequency power to drive Enseal electrosurgical instruments...." Mulloy Decl., Exs. 3-4.

> **f. …a plurality of non-conductive stop members disposed along the length of at least one of the seal surfaces of at least one of the jaw members such that the plurality of non-conductive stop members are disposed along the same plane on the seal surface with respect to one another…**

The stationary jaw member of the Enseal X1 has a plurality of stop members (7 total) disposed along the length of its sealing surface—one near the distal end, and three on each opposing side of the knife channel. Durfee Decl., ¶ 42. The stop members (red circles below) are disposed along the length and same plane as the surface of the stationary jaw of the Enseal X1.

Each stop member is separated from the stationary jaw electrode by a non-conductive plastic insulator. Durfee Decl., ¶ 43. As a result, the stop members do not conduct energy through tissue held between the seal plates and are non-conductive as set forth in the patent claim. *Id.*, ¶¶ 43-44.

> **g. …the non-conductive stop members configured to maintain a uniform distance between the jaw members along the length thereof...**

The non-conductive stop members of the Enseal X1 are configured to maintain a uniform gap distance between the jaw members along their length when in the claimed second position, including when tissue is held between the jaw members. Durfee Decl., ¶ 45. The measurements conducted by Covidien's expert confirms the gap distance between the Enseal X1 jaws is

uniform along the length of the jaws when in the second position—approximately .008 inches. *Id.*, ¶¶ 45-48.

h. …a knife disposed in operative communication with at least one of the jaw members and translatable to sever tissue disposed between jaw member.

The Enseal X1 includes a knife that translates through a knife channel in the jaw members to cut tissue held between the jaw members in a proximal-to-distal (i.e., forward) direction. Durfee Decl., ¶¶ 49-52. The knife is used to "cut" and "dissect" vessels and tissue during surgery. Mulloy Decl., Ex. 7 (510(k) summary).

***** ***** *****

The Enseal X1 thus includes each and every limitation of claim 1 of the '284 patent, and Covidien is likely to succeed on its claim for patent infringement.

2. Ethicon Will Not Be Able to Carry its Burden of Proving the '284 Patent Invalid By Clear and Convincing Evidence

Claim 1 of the '284 patent is presumed valid, and Ethicon must prove invalidity by clear and convincing evidence. 35 U.S.C. § 282; *see Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91 (2011). To the extent Ethicon "responds to [Covidien's] preliminary injunction motion by launching an attack on the validity of the patent[s], the burden is on [Ethicon] to come forward with evidence of invalidity, just as it would be at trial." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009).

Here, it is highly unlikely that Ethicon will be able to demonstrate invalidity by clear and convincing evidence. Ethicon has already *twice* attempted and failed to initiate IPR proceedings to invalidate claim 1 of the '284 patent. Ethicon's IPR petitions were both denied by the PTAB. Mulloy Decl., Exs. 6, 9. Having failed in its efforts to convince the PTAB to initiate an IPR proceeding regarding claim 1 of the '284 patent under the lower burden of proof applicable to those proceedings, *see* 35 U.S.C. § 316(e) ("In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence."), any argument by Ethicon that it can now demonstrate invalidity of claim 1 of the '284 patent by the higher clear and convincing evidence should be rejected.

The objective evidence on the face of the '284 patent further supports validity. The '284 patent was issued by the USPTO over hundreds of other United States patents, patent applications, foreign patent documents, and other printed publications considered during prosecution of the patent applications. *See* Mulloy Decl., Ex. 1, at pp. 1-9 (References Cited). The large number of prior art references already considered in issuing the '284 patent only further underscores that Ethicon cannot satisfy its burden to demonstrate invalidity.

B. Ethicon's Infringing Sales Are Causing Irreparable Harm To Covidien

To obtain a preliminary injunction, Covidien need only demonstrate that it is *likely* to suffer irreparable harm from Ethicon's infringement. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 8 ("This Court's frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction.") (emphasis in original). In patent cases, the loss of market share and business opportunities, as well as injury to reputation and goodwill, are types of irreparable harm that can warrant the issuance of a preliminary injunction. *See Trebro Mfg., Inc. v. Firefly Equip., LLC*, 748 F.3d 1159, 1170 (Fed.

Cir. 2014) (holding that "[t]he district court's blanket dismissal of evidence showing likely loss of market share and loss of access to customers was an error of law," because "[the Federal Circuit] has often explained that such factors are pertinent to the irreparable harm inquiry."); *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (recognizing that "loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm.") Here, Ethicon's aggressive marketing and sales of the Enseal X1 device are *already* causing, and will undoubtedly continue causing, irreparable harm to Covidien in the form of lost customers and market share, as well as injury to its reputation as the industry's most trusted and reliable advanced bipolar vessel sealer.

First, Covidien and Ethicon are direct competitors in the advanced energy surgical instrument market. Chindlund Decl., ¶ 20; *See Trebro Mfg., Inc.*, 748 F.3d at 1170 (emphasizing that the parties are "direct competitor[s]" in a three-player market as relevant to finding irreparable harm). [redacted] Covidien obtained and has maintained this relative market share for years because its LigaSure products, including the LigaSure Impact, are able to deliver consistent and reliable vessel seals to surgeons every time. *Id.*, ¶ 11. This is due in large part to Covidien's proprietary vessel sealing technology that is covered by the '284 patent.

Using Covidien's patented technology, Ethicon has positioned the Enseal X1 device directly against Covidien's leading LigaSure Impact product, and is promoting Enseal X1 as either comparable or superior to LigaSure Impact when it comes to vessel sealing performance. Ethicon's marketing materials explicitly target the LigaSure Impact and demonstrate that Ethicon is positioning the Enseal X1 to "replace" LigaSure Impact. Chindlund Decl., Ex. 6. Such direct

targeting is aimed at getting customers to switch from LigaSure Impact to Enseal X1, and chipping away at Covidien's reputation for delivering consistent and reliable vessel seals. *Id.*.

[redacted] If Ethicon is permitted to continue marketing and selling the Enseal X1 to "replace" LigaSure Impact, Covidien will continue to lose market share and business opportunities to a product that impermissibly uses Covidien's own patented inventions. In these circumstances, that alone is sufficient to establish irreparable harm. *See Trebro Mfg., Inc. v. Firefly Equipment, LLC*, 748 F.3d 1159, 1171 (Fed. Cir. 2014).

The long term consequences of Ethicon's marketing and sale of the Enseal X1 will be even more significant than Covidien's immediate loss of customers and corresponding market share for at least three reasons. First, medical device manufacturers like Covidien and Ethicon generally enter into long-term contracts (which can last several years) with their customers with respect to advanced energy vessel sealing product lines. Chindlund Decl., ¶ 42. Customer decisions made now will thus have a dramatic impact on Covidien's sales for years to come, and the market penetration that Ethicon is able to achieve by selling the Enseal X1 is likely to have long-term consequences for Covidien that are impossible to calculate at this time. *See Broadcom Corp. v. Qualcomm, Inc.*, 543 F.3d 683, 703-04 (Fed. Cir. 2008) (noting that "this difficulty in estimating monetary damages reinforces the inadequacy of a remedy at law").

The long-term consequences for Covidien are further compounded by Ethicon's existing relationships with Covidien's customers and the recent trend in the advanced energy instruments

space toward single-source suppliers for all advanced energy instruments. Chindlund Decl., ¶ 40. Ethicon is far and away the market leader in the ultrasonic segment of the advanced energy market. *See id.* As a result, one of Ethicon's stated strategies with Enseal X1 is to convert enough users from LigaSure to Enseal, such that Covidien's customers—hospitals, GPOs, and Independent Health Networks—will make a large-scale shift from being a dual-source customer (e.g., a customer of Ethicon ultrasonic instruments and Covidien's bipolar instruments) to a single-source customer (of only Ethicon devices). In its announcement following approval of the Enseal X1, Ethicon stated that "we are giving hospitals the ability to work with a ***single advanced energy provider***…" Chindlund Decl., Ex. 3 (emphasis added). Indeed, Ethicon is already successfully using the Enseal X1 to convince dual-source customers to stop purchasing LigaSure and principally become single-source Ethicon customers. *Id.*, ¶ 41.

[redacted]

[redacted] *See, e.g., Blackberry Ltd. v. Typo Prods. LLC*, 2014 WL 1318689, at *12 (N.D. Cal. Mar. 28, 2014) (finding "the requisite showing of irreparable harm" where the infringing keyboard in conjunction with an iPhone would allow users to forego buying a blackberry for typing and correspondence).

Second, when Ethicon sells the infringing Enseal X1 and touts its vessel sealing capability as being superior to that of LigaSure Impact, the market incorrectly sees Ethicon, rather than patentee Covidien, as the originator of superior advanced bipolar vessel sealing technology and the industry's innovator. *See* Chindlund Decl., ¶¶ 34-35. This misperception can have a lasting impact LigaSure's reputation among customers in the market. *See Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (identifying "damage to reputation" as a type of irreparable harm). LigaSure is known as being a consistent and reliable vessel sealer because of its patented technology. Chindlund Decl., ¶ 11. By suggesting that Enseal X1 is a superior vessel sealer to the LigaSure Impact, Ethicon is harming Covidien's reputation in the industry. *Id.*

Third, the Enseal XI large jaw is the first product in Ethicon's "new Enseal platform" and will undoubtedly be followed by other Enseal products embodying the infringing sealing technology. Chindlund Decl., ¶ 23. If Ethicon is not stopped from infringing, it will have carte blanche to market and sell additional infringing Enseal devices that wrongfully utilize Covidien's

own patented innovations while Covidien will continue to unfairly lose market share and suffer reputational loss.

Finally, Ethicon's continued infringement is likely to harm Covidien's overall business and undermine its investment in LigaSure. More than 500 Covidien employees are primarily focused on the LigaSure line of products, including product engineers, marketing managers, sales representatives, and manufacturing employees. Chindlund Decl., ¶ 49. Even a relatively modest reduction in Covidien's market share due to sales of the Enseal X1 could result in tens of millions of dollars in losses, places those jobs in jeopardy, and undermines Covidien's significant investment in the LigaSure line of products. *Id.*

C. There is a Nexus Between The Infringement and The Harm To Covidien

In order to establish that a "causal nexus relates the alleged harm to the alleged infringement," a patentee must "show 'some connection' between the patented feature[] and the demand for the infringing products," such that the "feature impacts customers' purchasing decisions" in some way. *Apple, Inc. v. Samsung Elecs. Co., Ltd.*, 809 F.3d 633, 641, 658 (Fed. Cir. Dec. 16, 2015). The patentee "does not need to establish that these features were the reason why consumers purchased the accused products," but only "that these features were related to infringement and were important to customers." *Id.* at 644 (emphasis in original). This can be done in "a variety of ways," including, for example, through evidence that the feature "makes a product significantly more desirable," or that its "absence … would make [the] product significantly less desirable." *Id.* at n.1*; accord. Veracode, Inc. v. Appthority, Inc.*, No. 12-10487-DPW, 2015 WL 5749435, at *47-48 (D. Mass. Sept. 30, 2015); *TransPerfect Global, Inc. v. MotionPoint Corp.*, No. C 10-2590, 2014 WL 6068384, at *6 (N.D. Cal. Nov. 13, 2014).

The nexus between Ethicon's infringement and the harm to Covidien is clear in this case. The '284 patent claims features that are critical to achieving a consistent and reliable vessel seal

during surgery, which is the principal purpose and driver of advanced bipolar vessel sealing instruments. Chindlund Decl., ¶ 11. Specifically, the stop member features claimed in the '284 patent are configured to maintain a uniform gap distance between the seal surfaces of the opposing jaw members—one of the two critical parameters that must be controlled in order to reliably seal large vessels. Durfee Decl., ¶¶ 55-57; *see* Mulloy Decl., Ex. 1, at Cols. 2:6-10 and 10:60-66. The relatively poor sealing performance of the previous Enseal product line (which did not utilize stop members on the lower jaw sealing surface) is a major reason why Ethicon has re-designed its Enseal device and incorporated Covidien's patented stop member technology into the Enseal X1 device. *See* Chindlund Decl., ¶¶ 21-22. Indeed, Ethicon markets its Enseal X1 product as purportedly providing "better sealing" than Covidien's LigaSure Impact device. Chindlund Decl., Ex. 5. The claimed patented features are not only demand drivers for Covidien's LigaSure products, but are crucial performance features of Ethicon's new Enseal X1 product. *Apple*, 809 F.3d at 644 n.1. There is a direct connection between Ethicon's infringement and Covidien's irreparable harm.

D. The Balance Of The Equities Weigh In Covidien's Favor

In deciding a preliminary injunction motion, "a court must consider the balance of hardships between the plaintiff and defendant." *Salinger v. Colting*, 607 F.3d 68, 80 (2d Cir. 2010). Here, Covidien will be substantially harmed by Ethicon's infringement. Ethicon has used Covidien's own patented technology to re-design its Enseal G2 product to compete directly with Covidien's LigaSure product, [redacted] Chindlund Decl., ¶¶ 16, 36. Indeed, Ethicon markets the Enseal X1 as an "alternative" to "replace" Covidien's LigaSure Impact device. Chindlund Decl., Ex. 6. "[R]equiring [Covidien] to compete against its own patented invention[s], with the resultant

harms described above, places a substantial hardship on [Covidien]." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1156 (Fed. Cir. 2011).

Any hardships to Ethicon, in contrast, are solely of its own making. An entity that "elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurfing Int'l, Inc. v. AMF, Inc.,* 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986). Indeed, Ethicon chose to proceed with the Enseal X1 despite being aware of the '284 patent and despite having failed in its multiple efforts to challenge the validity of that patent. *See* Mulloy Decl., Exs. 6, 9. Having elected to incur the risk of making and marketing an infringing product, Ethicon cannot demonstrate that the balance of equities tips in its favor. *See Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 345 (S.D.N.Y. 2006). Moreover, enjoining the Enseal X1 will not destroy Ethicon's business or even cause it significant harm. Ethicon has a relatively small percentage of the advanced bipolar vessel sealing market and can continue marketing its Enseal G2 devices if the Enseal X1 were not available. Chindlund Decl., ¶¶ 20-22. The balance of the equities strongly favors granting a preliminary injunction.

E. The Public Interest Favors Entry of a Preliminary Injunction

"[T]he public is best served by enforcing patents that are likely valid and infringed." *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006). Here, the public interest favors enforcing Covidien's patents in order to reward and incentivize Covidien's substantial research and development investments in innovation. Moreover, the public will not be harmed by an injunction in this case because the Enseal X1 product has only recently been approved and launched. *See Smith & Nephew, Inc. v. Biomet, Inc.*, 2005 WL 3132313, at *19 (D. Or. Nov. 21, 2005) (finding that "the public interest favors the grant of a preliminary injunction" in medical device case in part because defendant "Biomet's Sure Fire

device is too new to harm the public interest by the grant of preliminary relief."). There are also several alternative devices to serve the medical community, including Covidien's market leading LigaSure line of products. *See* Chindlund Decl., ¶¶ 20-22; s*ee e.g.*, *Celsis*, 664 F.3d at 931-32. The presence of other advanced bipolar surgical devices that have the same uses as the Enseal X1 confirms that a preliminary injunction will not harm the public interest. *See Acumed LLC v. Stryker Corp*., 551 F.3d 1323, 1331 (Fed. Cir. 2008).

V. CONCLUSION

For the foregoing reasons, Covidien respectfully requests that this Court enter a preliminary injunction preventing Ethicon from infringing claim 1 of the '284 patent by making, selling and marketing the Enseal X1 device.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, David J. Apfel, certify that this document filed through the ECF system will be served on May 2, 2017 electronically to the registered participants as identified in the Notice of Electronic Filing (NEF) and by first-class mail, postage prepaid on those identified as non-registered participants.

/s/ David J. Apfel
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